NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SUNOVIAN PHARMACEUTICALS INC.,	**Hon. Dennis M. Cavanaugh**
Plaintiff,	**OPINION**
v.	Civil Action No. 2:09-CV-01302 (DMC)(MF)
TEVA PHARMACEUTICALS USA, INC., *et al.*,	
Defendants.	

DENNIS M. CAVANAUGH, U.S.D.J.:

This matter comes before the Court on amended motion by Plaintiff Sunovian Pharmaceuticals, Inc. ("Plaintiff") for reconsideration pursuant to Local Civil Rule 7.1(i). (ECF Nos. 442, 445). Pursuant to FED. R. CIV. P. 78, no oral argument was heard. After carefully considering the submissions of the parties, and based upon the following, it is the finding of this Court that Plaintiff's Amended Motion for Reconsideration is **denied**.

I. BACKGROUND[1]

On October 13, 2011, Defendants Doctor Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively "DRL") filed a Motion for Summary Judgment in this matter, claiming the then-existing Amended New Drug Application ("ANDA") did not infringe upon

[1]The facts asserted herein are taken from the parties moving papers.

Plaintiff's Lunesta®, U.S. Patent No. 6,444,673 ("'673 Patent").

A Markman Hearing was held on April 10, 2012 in which the term "essentially free" was construed to mean "less than 0.25% of the levorotatory isomer." DRL's original ANDA provided for a Finished Product Specification of "not less than 0.3% and not more than 1.0%" of the levorotatory isomer zopiclone (also known as the R-Isomer). The limits were later restricted to the 0.0 to 0.6 percent in a revised ANDA submitted to the Food and Drug Administration ("FDA") on April 26, 2012. On May 25, 2012, this Court denied DRL's Motion for Summary Judgment of non-infringement without prejudice and permitted DRL to file a renewed motion provided it was accompanied by a certification assuring this Court that DRL would not market a product containing less than 0.3 percent of the levorotatory isomer of eszopiclone ("May 25th Order"). (ECF No. 437). DRL has thus submitted a certification stating it will not market an eszopiclone tablet with an levorotatory isomer content below 0.3 percent ("the Certification"). (ECF No. 449). The May 25th Order also prevented further briefing and declared that the renewed motion for summary judgment was to be decided upon consideration of the motion papers already before the Court and the Certification.

Plaintiff now moves for this Court to reconsider certain portions of the May 25th Order which could be read to suggest that the Certification by DRL providing it will not market generic eszopiclone tablets containing less than 0.3 percent levorotatory isomer would be sufficient to avoid infringement.

II. STANDARD OF REVIEW

Motions for reconsideration in this district are governed by L. Civ. R. 7.1(i). See U.S. v.

Compaction Sys. Corp., 88 F. Supp. 2d 339, 345 (D.N.J. 1999). Local Rule 7.1(i) requires that a movant submit "concisely the matter or controlling decisions which the party believes the [Judge] has overlooked." L. Civ. R. 7.1(i). A motion pursuant to Local Rule 7.1(i) may be granted only if (1) an intervening change in the controlling law has occurred; (2) evidence not previously available has become available; or (3) it is necessary to correct a clear error of law or prevent manifest injustice. Database Am., Inc. v. Bellsouth Adver. & Pub. Corp., 825 F. Supp. 1216, 1220 (D.N.J. 1993). Such relief is "an extraordinary remedy" that is to be granted "very sparingly." See NL Indus. Inc. v. Commercial Union Ins. Co., 935 F. Supp. 513, 516 (D.N.J. 1996). Local Rule 7.1(i) does not contemplate a recapitulation of arguments considered by the Court before rendering its original decision. See Bermingham v. Sony Corp. of Am., Inc., 820 F. Supp. 834, 856 (D.N.J. 1992), aff'd, 37 F.3d 1485 (3d Cir. 1994). In other words, a motion for reconsideration is not an appeal. It is improper on a motion for reconsideration to "ask the court to rethink what it ha[s] already thought through - rightly or wrongly." Oritani Sav. & Loan Ass'n v. Fidelity & Deposit Co., 744 F. Supp. 1311, 1314 (D.N.J. 1990)).

III. DISCUSSION

A. PLAINTIFF'S ARGUMENT REGARDING THE CERTIFICATION

Plaintiff argues that consideration of the Certification, in which DRL expressly confines itself to production of eszopiclone tablets with a levorotatory isomer content of greater than 0.3 percent, overlooks controlling legal precedent. (Pl.'s Am. Mot. Br. 2, June 6, 2012, ECF No. 446). Instead, Plaintiff contests the infringement analysis should be limited to a consideration of the ANDA filed by DRL with the FDA. (Id. at 5).

Title 35 of the United States Code Section 271(e)(2)(A) provides that it is an act of infringement to submit an ANDA "if the purpose of such a submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent." 35 U.S.C. § 271(e)(2)(C)(iii). In applying this statute, the reviewing court should focus on "what the ANDA applicant will likely market if its application is approved, an act that has not yet occurred." Bayer AG v. Elan Pharmaceutical Research Corp., 212 F.3d 1241, 1248 (Fed. Cir. 2000) (citing 35 U.S.C. § 271(e)(2)(A); Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1569 (Fed. Cir. 1997)). A court may properly consider the ANDA itself, materials submitted by the ANDA applicant in support of the ANDA, as any additional relevant material submitted by the applicant or the patent holder. Bayer AG, 212 F.3d at 1248-49.

In Bayer, Judge Schall noted that, when considering an ANDA for a well-defined compound, "the ultimate question of infringement is usually straightforward." Id. at 1249. The question presented in the instant case, however, is complex. If approved, the ANDA in question would permit DRL to produce eszopiclone with a levorotatory isomer content in the 0 to 0.6 percent range. DRL asserts that the ANDA provides a range that would allow them to manufacture eszopiclone tablets through two separate and distinct processes. "Process I" is undertaken to create an active pharmaceutical ingredient ("API") for DRL's own use containing a 0.3 to 0.6 percent levorotatory isomer. (Def.'s Opp. Br. 8, Jun. 19, 2012, ECF No. 452). "Process II" produces eszopiclone tablets containing less than 0.3 percent of the levorotatory isomer. (Id.) According to DRL, this process is exclusively used to manufacture a product for a

third party. (Id.) The Certification submitted by DRL states it will not market an eszopiclone tablet with an levorotatory isomer content below 0.3 percent. (Cappuccino Cert. ¶ 17, Jun. 8, 2012, ECF No. 449). Both internal regulations and the Certification preclude DRL from marketing a product made using Process II and marketing a tablet with a levorotatory isomer content under 0.3 percent.

As discussed, it is proper for this Court to consider "other relevant evidence submitted by the applicant or patent holder" in its infringement analysis. See Bayer AG v. Elan Pharmaceutical Research Corp., 212 F.3d 1241, 1248-49 (Fed. Cir. 2000). Despite the range provided for in the ANDA, DRL has obligated itself to comply with the Certification it provided this Court. The only options available to DRL are to comply with the Certification, and market a product that necessarily falls beyond the protection afforded by Plaintiff's patent, or decline to produce eszopiclone tablets at all. Plaintiff has thus failed to provide this Court with sufficient evidence to warrant reconsideration on that ground.

B. PLAINTIFF'S ARGUMENT REGARDING PREVIOUSLY UNAVAILABLE EVIDENCE

Plaintiff next purports to present new evidence in the form of a declaration and statistical analysis by Dr. Carl Peck, M.D., a former Director of the Center for Drug Evaluation and Research at the FDA. (Peck Decl., May 31, 2012, ECF No. 443-2). Dr. Peck concedes that no portion of the eszopiclone tablets sample tested contained a levorotary isomer content within the infringing range, yet concludes that there is a high probability that DRL will not be able to manufacture a product that replicates these non-infringing results. (Id. at ¶¶ 23-24). Dr. Peck relies on his computation of standard deviation to support his conclusion. (Id.) Essentially, the

levorotatory isomer content of the DRL's sample eszopiclone tablets ranged from 0.35 to 0.73 percent. (Id. at ¶ 23). Applying this range to a form of statistical analysis, Dr. Peck opines that a portion of DRL's final product will necessarily have a levorotatory isomer content below 0.3 percent, and would therefore infringe on the '673 Patent. (Id. at ¶ 24). However, DRL points out that applying the same statistical formula, some portion of the final product would contain less than 0 percent levorotatory isomer, a factual impossibility. (Chow Decl. ¶ 10, Jun. 19, 2012, ECF No. 452-2). Moreover, DRL claims that its acceptance range is inclusive of the percent relative standard deviation and the actual target levorotatory isomer content is roughly 0.45 percent. (Cappuccino Cert. ¶ 13). If that is assumed, the likelihood of DRL producing a product within the infringing range appears negligible. Plaintiff's presentation of Dr. Peck's calculation falls short of the heightened standard required for reconsideration.

Additionally, Nicholas Cappuccino, in his capacity as Vice President of Scientific Affairs, expressly asserts that DRL will not use "Process II" or any API produced using this process in the manufacture of its eszopiclone tablets. (Cappuccino Cert. ¶¶ 3-4). DRL further certified it would not market any eszopiclone tablets with a levorotatory isomer content below 0.3 percent. (Id. at ¶ 17). Failure to comply with the provisions of the Certification would make DRL susceptible to substantial penalties. The new evidence and statistical models offered by Plaintiff fail to provide sufficient grounds for reconsideration.

C. PLAINTIFF'S ARGUMENT REGARDING DOCTRINE OF EQUIVALENTS

Finally, Plaintiff argues that the product DRL seeks to produce will be equivalent to Plaintiff's Lunesta® for purposes of the infringement analysis. (Pl.'s Am. Mot Br. 13). Again,

Plaintiff relies on the declaration of Dr. Peck, which states that the two products deliver a similar amount of the eszopiclone and are "absorbed, distributed and eliminated in virtually the same manner" and ultimately concludes the products are bioequivalent. (Peck Decl. ¶ 36).

An ANDA may be filed if the active ingredient of the generic drug manufacturer's product is the "bioequivalent" of the listed drug. Bayer AG v. Elan Pharmaceutical Research Corp., 212 F.3d 1241, 1244 (Fed. Cir. 2000) (citing 21 U.S.C. § 355(j)(2)(A)(iv)). Assuming *arguendo* that the two products are the bioequivalent of one another, without more, Plaintiff is unable to meet their burden. The bioequivalency of an accused product with a product produced under the patent at issue is not sufficient to show equivalency for the purposes of an infringement analysis. Abbot Laboratories v. Sandoz, Inc., 566 F.3d 1282, 1298 (Fed. Cir. 2009). Whereas assessment of bioequivalency is a medical concern focused on determining whether two compounds are effectively the same for pharmaceutical purposes, equivalency for purposes of patent infringement requires an element-by-element comparison looking for equivalent function, way, and result. Id. Though Plaintiff has provided data suggesting DRL's product will benefit the end user in a manner that is substantially similar to Plaintiff's Lunesta®, it has fallen short of persuading this Court that, despite the Certification to the contrary, DRL is likely to market a product that is equivalent on an element-by-element basis.

IV. CONCLUSION

For the reasons stated, it is the finding of this Court that Plaintiff's Motion for Reconsideration is **denied**. An appropriate Order accompanies this Opinion.

Dennis M. Cavanaugh, U.S.D.J.

Orig.: Clerk
cc: All Counsel of Record
Hon. Mark Falk, U.S.M.J.
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